

## CLAIMS

We claim:

1. An anti-cancer composition for the purpose of treating at least one cell line of cancer in a mammalian patient comprising:

in at least one pharmaceutically acceptable carrier, a prophylactically effective amount of at least one selective COX-2 inhibitor, selected from the group of rofecoxib, celecoxib, etoricoxib, valdecoxib, and pharmaceutically acceptable flavanolignanes including silymarin, silibinin, silidianin, silicristin, dehydrosilybin, and phospholipid complexes of one of those flavanolignanes demonstrating selective COX-2 inhibition;

and a prophylactically effective amount of at least one HMG-CoA reductase inhibitor selected from the group of HMG-CoA reductase inhibitors particularly those known as statins, including lovastatin, simvastatin, pravastatin, compactin, atorvastatin calcium, cerivastatin sodium, fluvastatin sodium, and cholestin, to initially achieve a therapeutically effective change in cholesterol, and in combination with said selective COX-2 inhibitor to achieve a therapeutically effective change in progression of cancer.

2. An anti-cancer composition for the purpose of treating at least one cell line of cancer in a mammalian patient comprising:

in at least one pharmaceutically acceptable carrier, a prophylactically effective amount of at least one selective COX-2 inhibitor, selected from the group of rofecoxib, celecoxib, etoricoxib, valdecoxib, and pharmaceutically acceptable flavanolignanes including silymarin, silibinin, silidianin, silicristin, dehydrosilybin, and phospholipid complexes of one of those flavanolignanes demonstrating selective COX-2;

a prophylactically effective amount of at least one HMG-CoA reductase selected from the group of HMG-CoA reductase inhibitors known as statins, including lovastatin, simvastatin, pravastatin, compactin, atorvastatin calcium, cerivastatin sodium, fluvastatin sodium, and cholestin, to initially achieve a therapeutically effective change in cholesterol;

and a therapeutically effective amount of a glutathione pathway enhancing and

1 detoxifying compound in combination with said selective COX-2 inhibitor and  
2 said HMG-CoA reductase inhibitor to achieve a therapeutically effective change  
3 in progression of cancer.

4 3. An anti-cancer composition according to claim 2, further comprising:  
5 said glutathione pathway enhancing and detoxifying compound being cystine.

6 4. An anti-cancer composition for the purpose of treating at least one cell line of  
7 cancer in a mammalian patient comprising:

8 in at least one pharmaceutically acceptable carrier, a prophylactically effective  
9 amount of at least one selective COX-2 inhibitor, selected from the group of rofecoxib,  
10 celecoxib, etoricoxib, valdecoxib, and pharmaceutically acceptable flavanolignanes  
11 including silymarin, silibinin, silidianin, silicristin, dehydrosilybin, and phospholipid  
12 complexes of one of those flavanolignanes demonstrating selective COX-2 inhibition;

13 a prophylactically effective amount of at least one HMG-CoA reductase inhibitor  
14 selected from the group of HMG-CoA reductase inhibitors particularly those known as  
15 statins, including lovastatin, simvastatin, pravastatin, compactin, atorvastatin calcium,  
16 cerivastatin sodium, fluvastatin sodium, and cholestin, to initially achieve a  
17 therapeutically effective change in cholesterol,

18 and in at least one of said at least one carrier, an excipient to augment immune  
19 function, said excipient being characterized by an ability to be a glutathione pathway  
20 enhancing and detoxifying compound, said composition and said prophylactically  
21 effective amounts being combined to achieve a therapeutically effective change in  
22 progression of cancer.

23 5. The anti-cancer composition according to claim 4, further comprising:  
24 said excipient being cystine.

25 6. An anti-cancer composition for the purpose of treating at least one cell line of  
26 cancer in a mammalian patient comprising:

27 in at least one pharmaceutically acceptable carrier, a prophylactically effective  
28 amount of at least one selective COX-2 inhibitor, selected from the group of rofecoxib,  
29 celecoxib, etoricoxib, valdecoxib, and pharmaceutically acceptable flavanolignanes  
30 including silymarin, silibinin, silidianin, silicristin, dehydrosilybin, and phospholipid  
31 complexes of one of those flavanolignanes demonstrating selective COX-2 inhibition;

1 a prophylactically effective amount of at least one HMG-CoA reductase inhibitor  
2 selected from the group of HMG-CoA reductase inhibitors particularly those known as  
3 statins, including lovastatin, simvastatin, pravastatin, compactin, atorvastatin calcium,  
4 cerivastatin sodium, fluvastatin sodium, and cholestin, to initially achieve a  
5 therapeutically effective change in cholesterol,

6 and in at least one of said at least one carrier, a prophylactically effective amount  
7 of cystine to augment immune function which cystine is characterized by an ability to be  
8 a glutathione pathway enhancing and detoxifying compound, said composition and said  
9 prophylactically effective amounts being combined to achieve a therapeutically effective  
10 change in progression of cancer.

11 7. An anti-cancer composition for the purpose of treating at least one cell line of  
12 cancer in mammalian patient comprising:

13 in a pharmaceutically acceptable carrier, the combination of at least one HMG-  
14 CoA reductase inhibitor selected from the group of HMG-CoA reductase inhibitors  
15 known as statins, including lovastatin, simvastatin, pravastatin, compactin, atorvastatin  
16 calcium, cerivastatin sodium, fluvastatin sodium, and cholestin, beginning at a minimum  
17 recommended dose adjusted upward each six weeks by 10% within the therapeutic  
18 window of said HMG-CoA reductase inhibitor until LDL cholesterol has been lowered at  
19 least 10%; and

20 at least a minimum recommended dose of at least one selective COX-2 inhibitor,  
21 selected from the group of rofecoxib, celecoxib, etoricoxib, valdecoxib, and  
22 pharmaceutically acceptable flavanolignanes including silymarin, silibinin, silidianin,  
23 silicristin, dehydrosilybin, and phospholipid complexes of one of those flavanolignanes  
24 demonstrating selective COX-2 inhibition, said dose being adjusted upward each six  
25 weeks within the therapeutic window of said selective COX-2 inhibitor until at least two  
26 inflammatory response markers show therapeutic change: said at least two inflammatory  
27 response markers including upregulation of IL-12 and downregulation of IL-10; and

28 thereafter, until regression of tumor or a decrease in tumor progression, each said  
29 dose being adjusted upward on a six-week basis by at least 10% of the previous dose  
30 being given within the therapeutic window for each respective dose.

31 8. An anti-cancer composition for the purpose of treating at least one cell line of

1 cancer in mammalian patient comprising:

2 in a pharmaceutically acceptable carrier, the combination of at least one HMG-  
3 CoA reductase inhibitor selected from the group of HMG-CoA reductase inhibitors  
4 known as statins, including lovastatin, simvastatin, pravastatin, compactin, atorvastatin  
5 calcium, cerivastatin sodium, fluvastatin sodium, and cholestin beginning at a minimum  
6 recommended dose adjusted upward each six weeks by 10% within the therapeutic  
7 window of lovastatin until LDL cholesterol has been lowered at least 10%; and

8 at least a minimum recommended dose of at least one selective COX-2 inhibitor,  
9 selected from the group of rofecoxib, celecoxib, etoricoxib, valdecoxib, and  
10 pharmaceutically acceptable flavanolignanes including silymarin, silibinin, silidianin,  
11 silicristin, dehydrosilybin, and phospholipid complexes of one of those flavanolignanes  
12 demonstrating selective COX-2 inhibition, said dose being adjusted upward each six  
13 weeks within the therapeutic window of said selective COX-2 inhibitor until  
14 prophylactically effective upregulation of isoprostane and lipid peroxidation; and  
15 thereafter, until regression of tumor or a decrease in tumor progression, each said  
16 dose being adjusted upward on a six-week basis by at least 10% of the previous dose  
17 being given within the therapeutic window for each respective dose.

18 9. An anti-cancer composition for the purpose of treating at least one cell line  
19 of cancer in mammalian patient comprising:

20 in a pharmaceutically acceptable carrier, the combination of at least one HMG-  
21 CoA reductase inhibitor selected from the group of HMG-CoA reductase inhibitors  
22 known as statins, including lovastatin, simvastatin, pravastatin, compactin, atorvastatin  
23 calcium, cerivastatin sodium, fluvastatin sodium, and cholestin, beginning at a minimum  
24 recommended dose adjusted upward each six weeks by 10% within the therapeutic  
25 window of said HMG-CoA reductase inhibitor until LDL cholesterol has been lowered at  
26 least 10%; and

27 at least a minimum recommended dose of at least one selective COX-2 inhibitor,  
28 selected from the group of rofecoxib, celecoxib, etoricoxib, valdecoxib, and  
29 pharmaceutically acceptable flavanolignanes including silymarin, silibinin, silidianin,  
30 silicristin, dehydrosilybin, and phospholipid complexes of one of those flavanolignanes  
31 demonstrating selective COX-2 inhibition, said dose being adjusted upward each six

1 weeks within the therapeutic window of said selective COX-2 inhibitor until at least two  
2 inflammatory response markers show therapeutic change: said at least two inflammatory  
3 response markers including upregulation of IL-12 and downregulation of IL-10; and

4 thereafter, until regression of tumor or a decrease in tumor progression, each said  
5 dose being adjusted upward on a six-week basis by at least 10% of the previous dose  
6 being given within the therapeutic window for each respective dose; and

7 and in at least one of said at least one carrier, a prophylactically effective amount  
8 of cystine to augment immune function which cystine is characterized by an ability to be  
9 a glutathione pathway enhancing and detoxifying compound, said composition and said  
10 prophylactically effective amounts being combined to achieve a therapeutically effective  
11 change in progression of cancer.

12 10. An anti-cancer composition for the purpose of treating at least one cell line of  
13 cancer in mammalian patient comprising:

14 in a pharmaceutically acceptable carrier, the combination of at least one HMG-  
15 CoA reductase inhibitor selected from the group of HMG-CoA reductase inhibitors  
16 known as statins, including lovastatin, simvastatin, pravastatin, compactin, atorvastatin  
17 calcium, cerivastatin sodium, fluvastatin sodium, and cholestin beginning at a minimum  
18 recommended dose adjusted upward each six weeks by 10% within the therapeutic  
19 window of lovastatin until LDL cholesterol has been lowered at least 10%; and

20 at least a minimum recommended dose of at least one selective COX-2 inhibitor,  
21 selected from the group of rofecoxib, celecoxib, etoricoxib, valdecoxib, and  
22 pharmaceutically acceptable flavanolignanes including silymarin, silibinin, silidianin,  
23 silicristin, dehydrosilybin, and phospholipid complexes of one of those flavanolignanes  
24 demonstrating selective COX-2 inhibition, said dose being adjusted upward each six  
25 weeks within the therapeutic window of said selective COX-2 inhibitor until  
26 prophylactically effective upregulation of isoprostane and lipid peroxidation; and

27 thereafter, until regression of tumor or a decrease in tumor progression, each said  
28 dose being adjusted upward on a six-week basis by at least 10% of the previous dose  
29 being given within the therapeutic window for each respective dose, and

30 and in at least one of said at least one carrier, a prophylactically effective amount  
31 of cystine to augment immune function which cystine is characterized by an ability to be

1 a glutathione pathway enhancing and detoxifying compound, said composition and said  
2 prophylactically effective amounts being combined to achieve a therapeutically effective  
3 change in progression of cancer.

4 11. The anti-cancer composition according to claims 1-10, further comprising:  
5 lipoic acid.

6 12. The anti-cancer composition according to claims 1-10, further comprising:  
7 at least one dietary supplement to maintain adequate levels of Vitamin C, Vitamin  
8 E and Selenium.

9 13. The anti-cancer composition according to claims 1-10, further comprising:  
10 lipoic acid; and  
11 at least one dietary supplement to maintain adequate levels of Vitamin C, Vitamin  
12 E and Selenium.

13 14. A method of treating at least one cell line of cancer in a mammalian  
14 patient comprising:

15 Combining in a pharmaceutically acceptable carrier a prophylactically effective  
16 amount at least one selective COX-2 inhibitor, selected from the group of rofecoxib,  
17 celecoxib, etoricoxib, valdecoxib, and pharmaceutically acceptable flavanolignanes  
18 including silymarin, silibinin, silidianin, silicristin, dehydrosilybin, and phospholipid  
19 complexes of one of those flavanolignanes demonstrating selective COX-2 inhibition,  
20 within the therapeutic window for said selective COX-2 inhibitor;

21 and a prophylactically effective amount of at least one HMG-CoA reductase  
22 inhibitor selected from the group of HMG-CoA reductase inhibitors known as statins,  
23 including lovastatin, simvastatin, pravastatin, compactin, atorvastatin calcium,  
24 cerivastatin sodium, fluvastatin sodium, and cholestin, to initially achieve a  
25 therapeutically effective change in cholesterol, and in combination with said selective  
26 COX-2 inhibitor to achieve a therapeutically effective change in progression of cancer.

27 15. The method according to claim 14, further comprising the step:  
28 incorporating in at least one of said at least one carrier an excipient to augment  
29 immune function, said excipient being characterized by an ability to be a glutathione  
30 pathway enhancing and detoxifying compound. *cytotoxic*

31 16. The method according to claim 15, further comprising:

1           said excipient being cystine.

2           17.     A method of treatment of at least one cell line of cancer in a mammalian  
3 patient comprising:

4           administering at least a minimum recommended dose of in a pharmaceutically  
5 acceptable carrier;

6           administering at least a minimum recommended dose of rofecoxib in a  
7 pharmaceutically acceptable carrier in order to achieve a therapeutic change in cancer.

8           18.     The method according to claim 17, further comprising the step:  
9 incorporating in at least one of said at least one carrier an excipient to augment  
10 immune function, said excipient being characterized by an ability to be a glutathione  
11 pathway enhancing and detoxifying compound.

12           19. The method according to claim 18, further comprising:

13           said excipient being cystine.

14           20. A method of treatment of at least one cell line of cancer in a mammalian  
15 patient comprising:

16           administering a dose of lovastatin beginning at 10mg in daily amount in a  
17 pharmaceutically acceptable carrier;

18           administering a dose of rofecoxib beginning at 12.5 mg in daily amount in a  
19 pharmaceutically acceptable carrier,

20           adjusting said dose of lovastatin upward after six weeks within the therapeutic  
21 window of lovastatin until LDL cholesterol has been lowered at least 10%;

22           adjusting said dose of rofecoxib upward each six weeks within the therapeutic  
23 window for rofecoxib until prophylactically effective upregulation of isoprostane and  
24 lipid peroxidation; and

25           thereafter, until regression of tumor or a decrease in tumor progression, adjusting  
26 both doses upward on a six-week basis by at least 10% of the previous dose being given  
27 within the therapeutic window for each of rofecoxib and lovastatin.

28           21. The method according to claim 20, further comprising:

29           Combining a therapeutically effective amount of a glutathione pathway enhancing  
30 and detoxifying compound in combination with said rofecoxib and lovastatin to achieve a  
31 therapeutically effective change in progression of cancer.

1           22. The method according to claim 21, further comprising:

2           said glutathione pathway and detoxifying compound being cystine.

3           23.     A method of treatment of at least one cell line of cancer in a mammalian  
4 patient comprising:

5           administering a dose of lovastatin beginning at 10mg in daily amount in a  
6 pharmaceutically acceptable carrier;

7           administering a dose of rofecoxib beginning at 12.5 mg in daily amount in a  
8 pharmaceutically acceptable carrier,

9           adjusting said dose of lovastatin upward after six weeks within the therapeutic  
10 window of lovastatin until LDL cholesterol has been lowered at least 10%;

11          adjusting said dose of rofecoxib upward each six weeks within the therapeutic  
12 window for rofecoxib until at least two inflammatory response markers, tested each six  
13 weeks, show therapeutic change: said at least two inflammatory response markers  
14 including upregulation of IL-12 and downregulation of IL-10; and

15          thereafter, until regression of tumor or a decrease in tumor progression, adjusting  
16 both doses upward on a six-week basis by at least 10% of the previous dose being given  
17 within the therapeutic window for each of rofecoxib and lovastatin.

18          24. The method according to claim 23, further comprising:

19          Combining a therapeutically effective amount of a glutathione pathway enhancing  
20 and detoxifying compound in combination with said rofecoxib and lovastatin to achieve a  
21 therapeutically effective change in progression of cancer.

22          25. The method according to claim 24, further comprising:

23          said glutathione pathway and detoxifying compound being cystine.

24          26. The method according to claims 14–25, further comprising:

25          administering lipoic acid.

26          27. The method according to claims 14–25, further comprising:

27          administering dietary supplements to maintain adequate levels of Selenium,  
28 Vitamin C and Vitamin E.

29          28. The method according to claims 14–25, further comprising:

30          administering lipoic acid; and

31          administering dietary supplements to maintain adequate levels of Selenium,

Vitamin C and Vitamin E.

29. A method of manufacturing an anti-cancer combination comprising the following steps:

incorporating in at least one pharmaceutically carrier for cancer patients at least the lowest dose in the therapeutic window at least one HMG-CoA reductase inhibitor selected from the group of HMG-CoA reductase inhibitors particularly those known as statins, including lovastatin, simvastatin, pravastatin, compactin, atorvastatin calcium, cerivastatin sodium, fluvastatin sodium, and cholestin; and

incorporating in at least one pharmaceutically acceptable carrier for cancer patients at least the lowest dose in the therapeutic window of at least one selective COX-2 inhibitor, selected from the group of rofecoxib, celecoxib, etoricoxib, valdecoxib, and pharmaceutically acceptable flavanolignanes including silymarin, silibinin, silidianin, silicristin, dehydrosilybin, and phospholipid complexes of one of those flavanolignanes demonstrating selective COX-2 inhibition.

30. A method of manufacturing an anti-cancer combination comprising the following steps:

incorporating in at least one pharmaceutically carrier for cancer patients at least the lowest dose in the therapeutic window at least one HMG-CoA reductase inhibitor selected from the group of HMG-CoA reductase inhibitors particularly those known as statins, including lovastatin, simvastatin, pravastatin, compactin, atorvastatin calcium, cerivastatin sodium, fluvastatin sodium, and cholestin; and

incorporating in at least one pharmaceutically acceptable carrier for cancer patients at least the lowest dose in the therapeutic window of at least one selective COX-2 inhibitor, selected from the group of rofecoxib, celecoxib, etoricoxib, valdecoxib, and pharmaceutically acceptable flavanolignanes including silymarin, silibinin, silidianin, silicristin, dehydrosilybin, and phospholipid complexes of one of those flavanolignanes demonstrating selective COX-2 inhibition; and

incorporating in at least one of said at least one carrier an excipient to augment immune function, said excipient being characterized by an ability to be glutathione pathway enhancing and detoxifying compound.

31. The method according to claim 30, further comprising:

said excipient being cystine.

32. The method of manufacturing according to claims 29-31, further comprising:  
incorporating lipoic acid.

33. The method according to claims 29–31, further comprising:  
incorporating dietary supplements to maintain adequate levels of Selenium,  
Vitamin C and Vitamin E.

34. The method according to claims 29-31, further comprising:  
incorporating lipoic acid; and  
incorporating dietary supplements to maintain adequate levels of Selenium,  
Vitamin C and Vitamin E.

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